

REMARKS

Applicant has amended the claims to more precisely define the invention. In particular, claim 23 has been cancelled and claims 24 and 26 have been amended. In view of the amendments made to the claims, it is submitted that no new matter has been added to the application.

Claims 23, 26 and 27 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In support of the rejection, the Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is traversed and it is submitted that the claims are in full compliance with the written description requirements of 35 U.S.C. §112.

It is well-settled that the Examiner is charged with the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under the first paragraph 35 U.S.C. §112 for lack of adequate descriptive support and that this burden is not discharged merely by alleging that every nuance of the claims is not explicitly described in the specification. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996). Rather, the Examiner is obliged to provide a basis to support the determination that one having ordinary skill in the art would not have recognized from the disclosure a description of the invention defined by the claims. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Alton, supra*.

Whether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact. *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ2d 1227 (Fed. Cir. 1997). Also, the sufficiency of the description is measured from the point of view of one of ordinary skill in the art as of the time the description is filed. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915 (Fed. Cir. 2000). Compliance with the written description requirement is essentially a fact-based

inquiry that will “necessarily vary depending on the nature of the invention claimed.” *Vas-Cath Inc. v. Mahurkar, supra.*

In the November 6, 2003 Office Action, the Examiner alleged that the claims run afoul of 35 U.S.C. §112, ¶ 1 because “the claimed invention lacks adequate written description as required under current written description guidelines” “Written Description” Requirement, 66 Fed. Reg. 1,099 (Jan. 5, 2001) (“Guidelines”). Conspicuously absent from the Office Actions is any indication by the Examiner of any specific portion of the Guidelines relied upon to support the allegation that the claimed invention lacks adequate written description under the first paragraph of 35 U.S.C. §112. Should the Examiner remain of the position that the Guidelines have a bearing on the present claims, then it is requested that the specific portions of the Guidelines which the Examiner maintains are controlling in the present application be identified.

Concerning the Guidelines, the Examiner’s attention is directed to the following statement:

In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention. Guidelines at 1106 emphasis added.

At the outset, it is noted that the Examiner has not provided any evidence, or reasoning or scientific reasoning for that matter that explains why this portion of the Guidelines is inapplicable to the rejected claims. Specifically, the Examiner has not provided any evidence that the technology covered by the present claims is in its infancy or that the level of skill in the art is low. This is not surprising. A model for breeding hybrid corn was proposed as early as 1918 and the single cross hybrid model became the predominant model in the 1960s. In addition, a corn breeder typically has one or more advanced degrees and 5 or more years of experience. Accordingly, in the absence of any explanation why this portion of the Guidelines is irrelevant, it is submitted that the claims are in full compliance with the

Guidelines as well as the written description requirements of the first paragraph of 35 U.S.C. §112.

Assuming arguendo that the Examiner did provide such evidence and/or reasoning, the Examiner's attention is further directed to the following statement in the Guidelines that relate to inventions in emerging and unpredictable technologies:

Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied.
Guidelines at 1110 n. 52.

Conspicuously absent from the Office Actions is also an indication by the Examiner of any barriers that might exist to "actually" using the method of claim 24 to produce the product-by-process of claim 26, i.e., crossing an inventive corn plant belonging to a corn line selected from the group consisting of LS0414, LS1498 and LS288 with a different inbred parent corn plant to produce first generation hybrid corn seed. This is also not surprising. Such steps and therefore, such a product are well within the purview of a person having ordinary skill in this art. Accordingly, the Examiner has not only failed to identify any specific portions of the Guidelines relied upon to support the allegation that the claimed invention lacks adequate written description, but the Examiner has also not explained why the quoted portion of the Guidelines at 1106 is not controlling the present case, or why the Guidelines at 1110 n. 52 is inapplicable to the rejected claims. In the absence of such an explanation on the record, it is submitted that the claims are in full compliance with the written description requirements of the first paragraph of 35 U.S.C. §112 including the cited Guidelines.

Although the Examiner did not cite any judicial precedent, perhaps the Examiner had *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) in mind. In *Lilly*, under the particular facts of that case, it was determined that, *inter alia*, a product claim to cDNA encoding human insulin was not adequately described by a disclosure of a cDNA

sequence found in rats and a disclosure for only a generalized method for obtaining the human cDNA because:

an adequate written description of a DNA... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. (*Lilly*, 43 USPQ2d at 1404 emphasis added).

Thus, the patent-in-question in the *Lilly* case had claims to a product, i.e., DNA, and it was found that the product claim to DNA was inadequately described by (1) a description of a product outside the scope of the product claim and (2) only a generalized method of preparing the claimed product.

In contrast, each of the presently rejected claims 26 and 27 are product-by-process-claim. The Examiner has not explained why the *Lilly* rationale for product claims is applicable to product-by-process claims (note previous discussions of Guidelines). Further, the rejected claims are not directed to DNA, they are directed to F₁ hybrid seeds and plants. The Examiner has not explained why the *Lilly* rationale applies to corn breeding (again, note previous discussion of Guidelines). As explained above, corn breeding is a mature art and the level of skill in the art is high. And, unlike *Lilly*, with respect to claims 26 and 27, no barriers stand in the way of "actually" obtaining first generation hybrid corn seeds by the method of claim 24.

Thus, in *Lilly*, it was found that a DNA product claim was not adequately described by the description of a product outside the scope of the product claim and only a generalized method of preparing the claimed product; whereas it is factually un rebutted that the present claims are product-by-process claims in the field of corn breeding, the description of F₁ hybrid seed and plants in the application is identical to the scope of the product-by-process claim, and no evidence exists on the record that the disclosed method for crossing the inbred parent plants to produce the F₁ hybrid seed and plants in the application lacks the detail necessary to carry out the method as broadly as claimed.

The applicable legal standard is whether one having ordinary skill in the art would have recognized from the disclosure a description and possession of the invention defined by the claims. *Vas-Cath Inc. v. Mahurkar, supra*. Significantly, the Examiner does not point to anything in the originally filed disclosure which remotely suggests that a corn breeder would be unable to visualize or recognize the identity of the products covered by the product-by-process claims or, for that matter, that a corn breeder would not have recognized from the originally filed disclosure that Applicant had possession of the subject matter of the claimed products-by process.

Indeed, the same prior patent cited by the Examiner in the present case, namely U.S. Patent No. 5,569,820 to Stelpflug, contains claims to hybrid seed and hybrid plants. For example, independent claim 7 of Stelpflug reads:

7. Hybrid seed produced by hybrid combination of plants of inbred corn seed designated ZS1284 seed of which has been deposited in the ATCC under deposit number X and plants of another inbred line.

And dependent claim 8 reads:

8. Hybrid plant s grown from seed of claim 7.

Merely alleging that no phenotypic or genotypic information is included in the claims does not satisfy the Examiner's burden. It is, therefore, inconceivable that one having ordinary skill in the art would not have recognized from Applicant's originally filed disclosure a description of the invention defined by the claims, particularly in view of the cited issued U.S. patent that contains essentially the same terminology in the same field . Accordingly, reconsideration and withdrawal of this aspect of the rejection under 35 U.S.C. §112, first paragraph are requested.

Claims 26 and 27 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over U.S. Patent No. 5,569,820 to Stelpflug. This rejection is traversed and it is submitted that the claims now in the application are in full compliance with the requirements of 35 U.S.C. § 102(b) and § 103.

In rejecting a product-by-process claim under 35 USC §§102/103, it is well-settled that the Examiner is charged with the initial burden of establishing a *prima facie* case of anticipation and/or obviousness. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 78 (Fed. Cir. 1984); *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). In discharging that burden, the Examiner is required to provide a factual basis to support the conclusion that one having ordinary skill in the art would recognize that the product in the product-by-process claim is the same as or obvious from the product of the prior art. *In re Thorpe, supra.*; *In re Marosi*, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983).

Citing *In re Thorpe*, the Examiner stated that the claims run afoul of the requirements of 35 U.S.C. §§ 102/103 because:

While Stelpflug et al. do not teach that their F1 hybrid was produced by crossing a corn plant according to claim 6 with another, different corn plant, the claimed F1 hybrids seed and plant would read on any corn F1 hybrid seed or plant, as the claims do not set forth any characteristics that would distinguish them from other corn F1 hybrid seed or plants. (June 17, 2003 Office Action)

The Examiner's reliance upon *In re Thorpe, supra.* is misplaced. In *Thorpe*, under the particular facts of that case, it was determined by the Board that the applied prior art references disclosed the same product as that claimed but was prepared by a different process. Importantly, Thorpe did not contest the determination that the product of his process was different from the prior art product. In affirming the Board's determination, the Court of Appeals for the Federal Circuit noted that:

[t]he examiner compared the product of the prior art, and the product of Thorpe's process described by Thorpe, in accord with the standard examination practice, noting the similarity of reactants, reaction conditions, and properties. (*In re Thorpe*, 227 USPQ at 97, emphasis added).

The Examiner's reliance upon a decision where the Examiner compared the prior art product with the product covered by the product-by-process claim by noting the similarity of reactants, reaction conditions, and properties, thereby establishing a *prima facie* case is erroneous because, in the present case, the Examiner has ignored the claimed process steps, i.e., the actual inbred plants used as "reactants" in the present claims and has made no comparison between these and the inbred plants disclosed in Stelpflug. Instead, the Examiner chose to rely solely upon the F₁ hybrid claim language to the exclusion of the claim language that identifies the inbred parents of the F₁ hybrid. The Examiner's attempt to impress the *Thorpe* rationale on the present case is, therefore, misplaced and clearly erroneous.

Moreover, the Examiner's reliance upon *Thorpe* is misplaced because in that case the Applicant did not even assert that the product of his process was different from the product of the prior art. In contrast, Applicant submits that it is impossible that the claimed first generation hybrid corn seed produced by the method of claim 24, i.e., crossing an inventive inbred parent corn plant selected from the group consisting of LS0417, LS1498, and LS288 with the requisite seed profile with a different inbred parent corn plant and harvesting the resultant hybrid corn seed or an F₁ hybrid plant grown from such seed is identical to any Stelpflug hybrid that has ZS1284 as one parent, and any other inbred disclosed in Stelpflug as the other parent.

The Examiner is urged to appreciate that the exact composite of nuclear genes in a corn plant determines its genotype. Each gene occupies a particular position, or locus, in a specific chromosome and is replicated when the chromosome divides. The contrasting forms, called alleles encode for contrasting form of the character. With respect to the genotype of a first generation hybrid corn plant obtained by crossing two inbred parent plants, 50% of the alleles in the genotype of the hybrid plant are obtained from each inbred parent corn plant.

The first generation hybrid corn seed of claim 26 is obtained by, *inter alia*, crossing an inventive inbred parent corn plant selected from the group consisting of LS0417, LS1498, and LS288 with the requisite seed profile and a different inbred parent corn plant. As a result, the genotype of the resulting first generation hybrid corn seed includes 50% of the alleles from inbred corn plant LS0417, LS1498 or LS288 with the requisite seed profile. Simply stated, no combination of Stelpflug's inbred ZS1284 with any of Stelpflug's other disclosed inbreds will result in a first generation hybrid corn seed or plant with a genotype that includes 50% of the alleles from the inventive inbred corn plants. Whether Claim 26 contains a limitation about the genotype or phenotype of the F₁ hybrids is not relevant to this inquiry. The claimed F₁ hybrids cannot be identical to Stelpflug's hybrids. Applicant submits that since Stelpflug cannot disclose first generation hybrids having 50% of the alleles from the inventive inbred corn plant having seed with the requisite profile because Stelpflug fails to disclose inbred corn plant with seed having the claimed profile, Stelpflug does not disclose each feature of the claimed invention. Ergo, the Examiner's rejection under 35 U.S.C. § 102, as a factual matter, is clearly erroneous. Furthermore, since the Examiner has failed to provide a factual basis to support the conclusion that one having ordinary skill in the art would have been motivated to modify Stelpflug to arrive at the claimed invention, it cannot be concluded that the Examiner satisfied the initial burden of establishing a *prima facie* case of obviousness. Thus, the rejection under 35 U.S.C. §103 is also incorrect. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102/103 are requested.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the examiner. *In re Oetiker, supra.*; *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In rejecting a claim under 35 U.S.C. §103, the examiner must provide a factual basis to support the conclusion that one having ordinary skill in the art would have been motivated to modify the applied prior art to arrive at the

claimed invention. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 873 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Stelpflug discloses inbred corn line ZS1284 and broadly discloses that the invention also relates to a hybrid corn seeds and plants produced by crossing the inbred line ZS1284 with at least one other line. Stelpflug discloses inbred ZS1284 in certain hybrid combinations in, for example, Tables 5 and 6.

In Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1597 n. 42, 1 USPQ2d 1593, 1606 n. 42 (Fed. Cir. 1987), the Court underscored the necessity to resolve patentability issues with a view to the real world. Accordingly, it is necessary to interpret Stelpflug realistically through the eyes of one having ordinary skill in the art. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). It is submitted that one having ordinary skill in the art, out in the real world with Stelpflug in hand, would focus on the following shortcomings in Stelpflug.

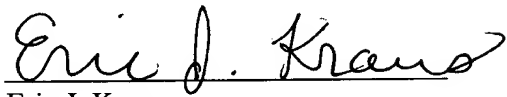
First, no disclosure exists in Stelpflug that inbred corn plant ZS1284 even has seed with the profile with a mean saturate content of less than about 7.0%, a mean oleic acid content of at least 64.9%, and a mean linoleic acid content of 24.7% or less, by weight relative to the total fatty acid content of said seed as required by claim 6 in the present application. Claim 26 explicitly requires that the F₁ hybrid seed be produced by crossing a plant according to claim 6 with a different inbred parent corn plant. The Examiner has not explained, and it is not apparent, how Stelpflug's inbred corn plant ZS1284 could be crossed with another inbred corn plant disclosed in Stelpflug to obtain an F₁ hybrid seed that obvious from the F₁ hybrid seed produced by the method of claim 24. Whether claim 26 sets forth any characteristics concerning the F₁ hybrid seed is immaterial because claim 26 requires that the F₁ hybrid seed be obtained by crossing a plant having a seed with a profile set forth in claim 6 and the Examiner has not shown that Stelpflug's seed has an identical or even similar profile for that matter. Because the Examiner has failed to provide a factual basis to support the conclusion that one having ordinary skill in the art would recognize that the F₁ hybrid

seed and plants, as claimed, are obvious from Stelpflug's disclosed F₁ hybrids, the rejection is improper and should be withdrawn. *In re Thorpe, supra.*; *In re Marosi, supra.*

Stelpflug provides, at the very best, nothing more than an invitation to try experimenting with ZS1284 as a parent in crosses with other inbred parents to obtain a first generation hybrid with the genotype, phenotype and attendant advantages that stem therefrom from the F₁ hybrid seed and plants of the present invention having a corn plant belonging to a corn line selected from the group consisting of LS0414, LS1498, and LS288 as a parent. This, of course, does not and cannot satisfy the Examiner's burden of showing *prima facie* obviousness. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 213 USPQ 81 (Fed. Cir. 1987). It is well established that an Examiner can satisfy this only by showing (1) that the prior art would have taught or suggested the claimed invention to one of ordinary skill in the art and (2) that one of ordinary skill in the art would reasonably expect that the method suggested by the prior art be successful. *In re O'Farrell*, 853 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988). In the present case, the Examiner has failed to show (1) that Stelpflug would have suggested the F₁ hybrid seed or plants, as claimed, or (2) a basis in the prior art for a reasonable expectation that such hybrid seed or plants could be successfully obtained. *In re Gangadharam*, 13 USPQ2d 1568, 1569 (Fed. Cir. 1989)(unpublished). Such silence in the applied prior art is no substitute for the factual support upon which the obviousness conclusion must rest. *In re Burt*, 356 F.2d 115, 148 USPQ 548 (CCPA 1966). The above-numerated voids in the applied prior art underscore the absence of a sufficient factual basis to support a *prima facie* case of obviousness. *In re Oetiker, supra.* Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 are requested.

In view of the amendments and remarks presented with this response, it is urged that the rejections of record are overcome and the present application is in condition for allowance. Favorable consideration of this application is requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Eric J. Kraus". The signature is written in dark ink and is positioned above a horizontal line.

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